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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,534	11/27/2001	Bernhard Homey	DX01342	2027
28008	7590	03/15/2004	EXAMINER	
DNAX RESEARCH, INC. LEGAL DEPARTMENT 901 CALIFORNIA AVENUE PALO ALTO, CA 94304			KEMMERER, ELIZABETH	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/995,534

### Applicant(s)

HOMEY ET AL.

### Examiner

Elizabeth C. Kemmerer, Ph.D.

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10,13,14 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10,13,14 and 16-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application, Amendments And/Or Claims***

The amendment received 23 January 2004 and the Information Disclosure Statement of 16 January 2004 have been entered in full into the record.

Claims 1-9, 11, 12 and 15 are canceled. Claims 10, 13, 14 and 16-26 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

The requirement for a new title as set forth at p. 3 of the previous Office Action (Paper No. 11, 18 July 2003) is *withdrawn* in view of the amendment replacing same (Amendment and Response received 23 January 2004).

The objection to claim 18 for informalities as set forth at p. 3 of the previous Office Action (Paper No. 11, 18 July 2003) is *withdrawn* in view of the amended claim (Amendment and Response received 23 January 2004).

### ***35 U.S.C. § 112, First Paragraph***

Claims 10, 13, 14 and 16-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention. The basis for this rejection is set forth at pp. 3-5 of the previous Office Action (Paper No. 11, 18 July 2003).

Applicant's arguments (Amendment and Response received 23 January 2004) have been fully considered but are not found to be persuasive for the following reasons.

Applicant argues that the Office Action's criticism of the specification not hypothesizing what role XCL1 plays in wound healing is irrelevant, since the inventor need not know how or why his invention works. Applicant cites case law in support of this argument at p. 5 of the response. The examiner takes no issue with Applicant's statement of the case law. However, one of the factors to be considered when determining whether undue experimentation would be required of the skilled artisan to make and/or use the claimed invention (i.e., whether or not the claimed invention is enabled) is the amount of direction or guidance provided by the specification. In the instant application, the prior art indicates that XCL1 is not used to accelerate wound healing, but can be used to kill cells, such as tumor cells (Hedrick et al., of record). The specification provides no guidance regarding how to administer a protein known for its cell-killing activity in a way that allows for accelerated wound healing, as required by the claims. A disclosure of a mechanism of action would have been probative, but is certainly not required. The point that was made in the office action was with respect to the lack of detailed guidance in the specification.

Applicant argues that Hedrick et al. do not teach against administering XCL1 to enhance cell growth. Applicant characterizes Hedrick et al. as being silent with respect to XCL1's wound healing activity. Applicant argues that the Hedrick et al. suggest that

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the local cellular environment dictates whether XCL1 activity is or is not desirable. This has been fully considered but is not found to be persuasive. Hedrick et al. clearly disclose that administration of XCL1 is desirable at a site where tumor cells should be killed, and that antagonists of XCL1 should be administered at a site where transplanted cells are to be kept alive. This counters the specification's assertion that XCL1 can be used to accelerate wound healing, which involves keeping cells alive and promoting their growth and differentiation. The specification provides no guidance regarding what local cellular environment would allow XCL1 to display wound healing activity.

Applicant provides two references as supporting the nexus between XCL1 and wound healing. These references have been fully considered but are not found to support the specification's assertion that XCL1 can be used to accelerate wound healing. The first reference, Boismenu et al. (1996, J. Immunol. 157:985-992) disclose that XCL1 is inducible in dendritic epidermal T cells and intestinal intraepithelial T cells. However, Boismenu et al. do not disclose that XCL1 can accelerate wound healing, but can chemoattract T cells. This is no different from the disclosure of Hedrick et al. The second reference, Huang et al. (2001, Biochem. Biophys. Res. Commun. 281:378-382) disclose that XCL1 can chemoattract B lymphocytes, NK cells and neutrophils, suggesting a role in inflammatory and immunological responses. Huang et al. do not suggest a role for XCL1 in wound healing. As discussed in the previous Office Action, chemoattraction of NK cells, as well as T and B lymphocytes and neutrophils, can be beneficial to a patient in fighting infection. However, the claims are not directed to a method of inhibiting or reducing the incidence of infection. Rather, the claims require

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that the administration of XCL1 results in accelerated wound healing *per se*. This is not supported by the specification or any evidence of record.

### **Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ECK

A handwritten signature in black ink that reads "Elizabeth C. Kemmerer". The signature is written in a cursive, flowing style.

ELIZABETH KEMMERER  
PRIMARY EXAMINER